

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA

v.

LAUREN STEVENS,

Defendant.

)
) **FILED UNDER SEAL**
)
)

) **No. 10-cr-694-RWT**
)
)
)
)
)

**DEFENDANT'S RESPONSE TO UNITED STATES'
MOTION IN LIMINE AND NOTICE OF POTENTIAL EVIDENTIARY ISSUES**

Defendant Lauren Stevens, through counsel, respectfully responds to the United States' Motion in Limine and Notice of Potential Evidentiary Issues (ECF No. 76). Through its motion, the government seeks to exclude thirteen categories of evidence, and raises additional evidentiary issues. While Ms. Stevens will address each item in turn, the following are true for all evidentiary issues raised by the government: (1) any evidence offered by Ms. Stevens will be relevant for a proper purpose and will be offered consistent with the Federal Rules of Evidence; (2) the admissibility of each piece of evidence will depend on an individualized assessment of the evidence, foundation, context, and purpose at the time the evidence is introduced; thus, it would be premature to make any definitive evidentiary rulings now; and (3) the admissibility of each piece of evidence will also depend on the extent to which the government's arguments and evidence "open the door" to certain issues.

Ms. Stevens hereby addresses each of the categories of evidence the government moves to exclude:

1. That the government did not indict other individuals.

Ordinarily, the government's charging decisions for other individuals are not admissible, for the reasons the government has explained. Gov. Mot. in Limine and Notice of Potential Evid. Issues at 1-2. Here, however, the government expressly contends that other attorneys were participants in the alleged crime, and it relies on that contention to move to exclude an advice-of-counsel defense. *See* Gov. Adv. of Counsel Mot. at 17 (ECF No. 19). Where the government has made it relevant whether witnesses were participants in a crime, and seeks an advantage based on a contention that they were, the fact that the government has not charged any of those individuals is a fair and relevant response to the government's contention.

2. Any potential punishment or collateral impact to which the defendant may be subject if she is convicted.

Ms. Stevens does not anticipate eliciting evidence of this nature. However, to the extent that the government may open the door on this issue, a definitive ruling would be premature.

3. Any consequences the defendant may have suffered as a result of being indicted or, prior to indictment, as a result of being identified as a target of a federal criminal investigation.

Ms. Stevens does not anticipate eliciting evidence of this nature. However, to the extent that the government may open the door on this issue, a definitive ruling would be premature.

4. References in opening, closing, or otherwise to personal facts of the defendant's life (including identification of family members in the courtroom) unless a witness will testify to such facts.

During her opening statement, Ms. Stevens' counsel should have latitude to briefly discuss her background, while still preserving her right to decide at the time of the defense's case

whether or not to testify. The Fourth Circuit has stated that “[t]he very purpose of an opening statement is to inform the jury how the case developed, its background and what will be attempted to be proved.” *Butler v. United States*, 191 F.2d 433, 435 (4th Cir. 1951); accord *United States v. Locust*, 95 Fed. Appx. 507, 514 (4th Cir. 2004) (quoting *Butler*); see also *Maxworthy v. Horn Elec. Serv.*, 452 F.2d 1141, 1143-44 (4th Cir. 1972) (because an opening statement is not evidence, it need only exclude “reference to matters that counsel knows he cannot prove or would be inadmissible”); *United States v. De Peri*, 778 F.2d 963, 978-79 (3rd Cir. 1985) (same). A brief discussion of Ms. Stevens’ background is important to the jury’s understanding of the case. Ms. Stevens does not intend to introduce family members during her opening statement.

In seeking to exclude any reference to Ms. Stevens’ personal background at trial, the government relies on cases that relate only to closing arguments. Specifically, the cases the government cites concern prosecutorial misconduct based on making arguments during closing that were not based on evidence before the jury at trial. For example, in *United States v. Wilson*, the prosecutor’s argument relating to an uncharged and unproven murder was “not based on record evidence or any reasonable inference that could be drawn from it.” 135 F.3d 291, 298 (4th Cir. 1998). Closing arguments, of course, should address facts in evidence. However, counsel during opening statements should have some latitude to address background information.

5. Other good acts and/or truthfulness of the defendant, except as admissible under Federal Rule of Evidence 404(a)(1) or 608(a).

Any evidence of other good acts and truthfulness of Ms. Stevens will be presented only for relevant and proper purposes. Ms. Stevens will of course adhere to the Rules of Evidence.

6. Alleged corrective actions taken by the defendant after receipt of the letter from the Food and Drug Administration (“FDA”), except as such actions demonstrate knowledge of off-label promotion, are otherwise intertwined with relevant evidence, or are reflected in the letters.

The government has indicated it intends to prove, under the rubric of motive, that Ms. Stevens made false statements to the FDA to hide larger evidence of off-label promotion generally at GlaxoSmithKline (“GSK”). *See* Gov. Opp. to Def. Mot. in Limine at 3 (ECF No. 73) (“The United States plans to introduce evidence of GSK’s off-label marketing of drugs other than Wellbutrin, and that evidence speaks to the defendant’s mental state and motive.”).

Ms. Stevens has filed a separate motion in limine to limit what the government offers in that regard under Rules 402 and 403, to avoid a lengthy sideshow at trial involving uncharged conduct regarding other drugs, and to avoid the possibility of Ms. Stevens being convicted based on uncharged conduct rather than what the Indictment alleges regarding Wellbutrin. Def. Corr. Mot. in Limine to Excl. Evid. Outside Scope of Allegs. (ECF No. 47).

However, to the extent the government is permitted to admit evidence or to present argument regarding Ms. Stevens’ knowledge of off-label promotion at GSK, and her motive to hide it, Ms. Stevens is entitled to respond with evidence to show that it was her belief and intention for GSK to *comply* with the law regarding off-label promotion. The government cannot try to prove an alleged course of nefarious conduct above and beyond the charges, under the rubric of “motive,” without Ms. Stevens being able to respond.

The government’s asserted exception for “demonstration of knowledge of off-label promotion” seems to suggest that the government wants to have it only one way—evidence of other promotion, whether on-label or off-label, may be admitted only by the government to show guilt,

but not by Ms. Stevens to counter the government's charges. Admissibility is not a one-way ratchet, and Ms. Stevens must be free to rebut *all* of the government's accusations, including those presented as evidence of "motive" that go above and beyond the conduct charged in the Indictment.

Finally, corrective actions taken by Ms. Stevens at any time are likely to be relevant in this matter as circumstantial evidence of the Ms. Stevens' actual beliefs regarding whether GSK's policies were intended to deter off-label promotion of Wellbutrin. The defense expects there to be evidence that in instances where Ms. Stevens became aware of individuals engaged in off-label promotion, that she took corrective measures. Such actions would constitute significant evidence of Ms. Stevens' belief that GSK, as a company, did *not* have a program of promoting Wellbutrin for obesity (an indication not included in the product's labeling material), and as such tend to contradict the government's interpretation of the allegedly falsified letters sent to FDA.

7. That the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") took no formal action against the defendant or GSK.

The fact that DDMAC took no formal action against Ms. Stevens or GSK is relevant and material to Ms. Stevens' defense and should not be excluded. This fact is circumstantial evidence that is relevant as to whether GSK's statements were material, and to whether Ms. Stevens submitted to FDA information that put GSK at risk of potential regulatory action. The latter is relevant in that it has some tendency to make facts more or less probable with regard to whether the statements at issue in the Indictment were in fact misleading.

For example, the defense contends that the letters submitted to FDA by Ms. Stevens contained significant admissions of wrong-doing by GSK, and thus tend to contradict the government's theory that the GSK team submitting the letters was prepared to willfully lie to conceal

misdeeds by the company. Statements by FDA witnesses regarding the lack of FDA enforcement based on what the letters revealed support the defense's position, and are thus admissible as relevant to the defense. For example, GSK disclosed in the March 28, 2003 letter that topics for 75 presentations sponsored by the company included terms that could be outside the approved indication for Wellbutrin SR—*i.e.*, had off-label titles. The lead FDA investigator, Leslie Frank, has since stated in an interview with the prosecution that the only reason that FDA did not take regulatory action on what Ms. Stevens disclosed was the pendency of the DOJ investigation.¹ This and similar testimony and other evidence clearly are admissible as tending to support the defense's contention that damaging information was voluntarily provided.

8. Why the FDA did not meet with the defendant after her May 21, 2003 letter, why the FDA did not further respond to the defendant's requests for a meeting after her May 21, 2003 letter, or communications between the FDA and the Department of Justice regarding the Department's opening of an investigation.

Ms. Stevens' position as to the relevance of such information was discussed in detail in her Memorandum in Support of Defendant's Motion to Compel Discovery and Disclosure of Material and/or Exculpatory Information at 5-12 (ECF No. 38) and Defendant's Reply in Support of Defendant's Motion to Compel Discovery and Disclosure of Material and/or Exculpatory Information at 4-9 (ECF No. 69). Such evidence is relevant and critical to the jury's assessment of Ms. Stevens' intent because such evidence determines the reasonableness of one of Ms. Stevens' central defenses—that her responses to the FDA were premised on an expectation as of May 2003 that a face-to-face meeting with FDA would be convened. As stated

¹ See Memorandum of Interview of Leslie Frank (March 20, 2009) ("They would have requested the slides from the presentations and would have likely issued a Warning Letter, if the DOJ investigation was not already ongoing.")

in her reply in support of her Motion to Compel Discovery, “it is one thing for Ms. Stevens to claim that FDA simply failed to answer her requests—it is another thing entirely for the jury to know the reasons behind FDA’s failure to respond Consequently, evidence of the ‘why’ behind FDA’s actions is of utmost importance to Ms. Stevens’ defense.” Def. Reply in Supp. of Mot. to Compel at 7-8 (ECF No. 69).²

9. That GSK ultimately produced documents, including the doctors’ slide sets, in response to subpoenas issued as part of the Department of Justice investigation.

The fact that the documents that are the subject of the obstruction of justice counts, based on their non-production to FDA, were maintained at GSK, and were produced to the Department of Justice pursuant to a subpoena issued in connection with a broad investigation of GSK addressing multiple products and issues, is relevant and critical to an assessment of Ms. Stevens’ state of mind at the time she engaged in allegedly criminal conduct.

To support a conviction on Counts One and Two, the government must prove that Ms. Stevens withheld documents and information with the intent to obstruct the FDA inquiry. Ms. Stevens is entitled to prove to the jury that she did not wrongfully intend to conceal the doctors’ slide decks from the FDA. The preservation of these documents, including records of discussion of these documents—by both Ms. Stevens and the rest of the GSK legal team—is highly probative of Ms. Stevens’ lack of intent to obstruct the FDA investigation. In addition, fairness requires that Ms. Stevens be allowed to make clear that the slide sets were preserved in light of the Indictment’s allegations of document alteration, concealment, cover-up, and destruction

² An unsealed version of this document will be released shortly pursuant to the Court’s directions at the hearing on March 17.

10. The alleged percentage of off-label sales of Wellbutrin for weight loss or the treatment of obesity.

The government alleges that Ms. Stevens made false statements to the FDA, and concealed documents and information from FDA, to hide the extent of GSK's off-label promotion of Wellbutrin for weight loss or the treatment of obesity. *See* Ind. ¶ 25; *see also* Gov. Opp. to Def.'s Mot. in Limine at 5 (ECF No. 73) (arguing about "just how important and big a problem the defendant was hiding"). In addition, the government has indicated it intends to argue the theory of "conscious avoidance": it will seek to convince the factfinder that it should infer Ms. Stevens knew of off-label promotion of Wellbutrin because the "facts . . . were staring her in the face" and she deliberately avoided learning the truth. Gov. Opp. to Def. Mot. in Limine at 8-11 (ECF No. 73). Accordingly, evidence that the percentage of off-label sales of Wellbutrin for weight loss or obesity treatment was miniscule is relevant both directly to refute the government's allegations that Ms. Stevens sought to hide allegedly large-scale off-label promotion violations at GSK, and to counter the government's contention that evidence of such off-label promotion was so obvious she must have deliberately disregarded it.

11. Alleged evidence demonstrating that Wellbutrin is safe and effective for off-label uses.

A definitive ruling on this issue is premature. Should the government argue, for example, that GSK's off-label promotion of Wellbutrin created a public safety risk, fairness dictates that Ms. Stevens must be allowed to rebut this argument with evidence, including expert testimony, describing the practice of off-label prescription and the extent of, or lack of, any public safety risk regarding Wellbutrin, in order to prevent the government from confusing the issues or misleading the jury with an inaccurate picture of risk to public health.

Moreover, the current case's focus on the regulation of "off-label" promotion will address in detail the question of when a representative of a drug company legitimately can discuss indications for which a drug is not approved. Relevant testimony will include the fact that while a drug company may not promote sales of a product for indications other than those approved on the label, that doctors may (and often do) prescribe products for indications not approved by FDA. This testimony is relevant to the fact that doctors who attend promotional meetings may legitimately have questions about off-label uses; and that under FDA regulations, representatives of the company may legitimately respond to independent questions asked by treating physicians, even if the questions seek information about use of the product for off-label indications. This fact in turn relates to the fact that a doctor may legitimately include in his slide decks slides that touch on off-label indications, but not use such slides except when asked by a third-party physician. The latter point is directly relevant to the issue of why the GSK legal team elected in May 2003 not to produce the slide decks now at issue, in the hope that they could explain to FDA the equivocal nature of slides that appeared to address off-label indications, but that might nevertheless be in full compliance with FDA rules on off-label promotion.

12. That the defendant was invited to speak at conferences regarding compliance with food and drug laws and/or was commended for her participation in such events by FDA employees or former FDA employees.

Ms. Stevens does not anticipate eliciting evidence regarding specific instances of her positive conduct in complying with food and drug laws or participating in industry conferences. However, to the extent that the government may open the door on this issue, a definitive ruling would be premature. For example, if the government attempts, in violation of Federal Rule of Evidence 404, to characterize Ms. Stevens as an individual prone to misleading the FDA, then

fairness dictates that Ms. Stevens be given an opportunity to rebut this improper characterization with testimony regarding Ms. Stevens' positive reputation among the regulatory community.

13. The defendant's own out-of-court statements when offered by the defendant.

A blanket ruling on the admissibility of all of Ms. Stevens' prior statements, whether written or oral, formal or informal, would be highly premature. Under Federal Rule of Evidence 803, many of Ms. Stevens' out-of-court statements may be admissible because they are probative of her state of mind. In addition, a number of Ms. Stevens' written statements may qualify for exception from the hearsay prohibition as recorded recollections and business records, or under the rule of completeness where the government offers only portions of a written statement.

The government alleges that Ms. Stevens knowingly and willfully made false statements to the FDA. Ms. Stevens must be able to defend herself against such allegations by introducing contemporaneous out-of-court statements that evidence her state of mind or serve as circumstantial evidence of whether or not she held the wrongful intent required for conviction under the charged offenses. Insofar as the government contends that Ms. Stevens cannot admit any of her former statements without taking the stand and subjecting herself to cross-examination, such an attempt to use expansive interpretation of the hearsay prohibition to drive Ms. Stevens to the witness stand would infringe on Ms. Stevens' Fifth Amendment right. Ms. Stevens has a Due Process right to a fair trial, including the right to put on her defense, and the right to decide whether or not to testify. Those rights cannot be set at odds with one another, nor can Ms. Stevens be denied the right to introduce evidence that is fundamental to her defense. *See United States v. Sanders*, 862 F.2d 79, 84 (4th Cir. 1988) (holding it was reversible error to preclude the admission of non-hearsay state of mind evidence where such statements would have supported the main theory of the defense).

Potential Evidentiary Issues

The government also seeks for the Court to rule or provide guidance on a number of potential evidentiary issues, each of which Ms. Stevens addresses in turn:

A. Handwritten Notes:

1. The defendant's handwritten notes:

Ms. Stevens does not object to the government's description of the admissibility of Ms. Stevens' own handwritten notes.

2. Handwritten notes of individuals who are called as witnesses:

It is premature to determine whether the handwritten notes of individuals who are called as witnesses are necessarily admissible under the various exceptions to the hearsay rule specified in the government's motion. Any notes offered first must be authenticated by the witness who created them, and who can describe the reason and context for creation of any notes offered.

3. Handwritten notes of individuals who are not called as witnesses:

Ms. Stevens agrees that any ruling regarding the admissibility of handwritten notes in this category would be premature.

B. The Proffer Agreement:

The government is correct that proffer agreements are enforceable according to their terms. Gov. Mot. at 9 (quoting *United States v. Lopez*, 219 F.3d 343, 346 (4th Cir. 2000)). This is true not only as a matter of ordinary contract principles, but also to protect the defendant's constitutional rights, and as a matter of the government's honor. See *United States v. Peglera*, 33 F.3d 412, 413-14 (4th Cir. 1994) (noting that "a government that lives up to its commitments is the essence of liberty under law"); *United States v. Harvey*, 791 F.2d 294, 300 (4th Cir. 1986) (enforcement of plea agreements reflects not only constitutional concerns but also concerns for the "honor of the government" and "public confidence in the fair administration of justice").

Where a defendant forgoes her constitutional rights (here, the right to remain silent in the face of government investigation) in reliance on the government's promise, the government will be held strictly to the terms of its promise. *See, e.g., Santobello v. New York*, 404 U.S. 257, 261-63 (1971); *Harvey*, 791 F.2d at 300-03; *see also United States v. McQueen*, 108 F.3d 64, 66 (4th Cir. 1997).

In addition, any ambiguities in the agreement are construed against its drafter, the government. *See Harvey*, 791 F.2d at 300-01; *accord United States v. Jordan*, 509 F.3d 191, 195-96 (4th Cir. 2007); *United States v. Wood*, 378 F.3d 342, 348 (4th Cir. 2004). This is true both as a matter of ordinary contract interpretation, *see Harvey*, 791 F.2d at 301 (citing Restatement (Second) of Contracts § 206 (1981)), and because "both constitutional and supervisory concerns require holding the Government to a greater degree of responsibility than the defendant . . . for imprecisions or ambiguities" in agreements whereby defendants waive constitutional protections. *Id.* at 300 (collecting cases); *accord Jordan*, 509 F.3d at 195-96; *Wood*, 378 F.3d at 348.

Here, the government's proffer agreement with Ms. Stevens promised that the government will not use Ms. Stevens' proffer statements against her

except for purposes of cross-examination and/or impeachment
**should she offer in any proceeding statements or information
different from** statements made or information provided by her
during the proffer.

Gov. Mot. at 9 (quoting proffer agreement) (emphasis added).

These terms differ from the terms of the agreements analyzed in the cases the government cites, and it is the terms of *this* agreement that control in this case. *See Lopez*, 219 F.3d at 346-47 (rejecting government's reliance on Seventh Circuit cases because the terms of the proffer agreement in *Lopez* were narrower than those in the Seventh Circuit cases the government cited).

The government contends it will be entitled to use Stevens' proffer statements for cross-examination or impeachment of defense witnesses if "Stevens or her counsel make[s] arguments or present[s] evidence at trial that is inconsistent with what she said during her proffers." Gov. Mot. at 10. The government is wrong for several reasons.

First, the agreement here is not triggered by argument of counsel, as the government contends. In the Third Circuit and Seventh Circuit cases the government cites, the proffer agreements specifically allowed the government to use the proffer statements to rebut evidence *or argument* by the defense. *See Hardwick*, 544 F.3d at 570 ("The terms of the waiver here were expansive, allowing the Government to use Murray's proffer statements not only to cross-examine him, but also 'to rebut *any* evidence **or arguments** offered on [his] behalf.'") (italics in original; bold emphasis added); *United States v. Krilich*, 159 F.3d 1020, 1024 (7th Cir. 1998) (proffer agreement allowed use of statement if defendant "should . . . subsequently testify contrary to the substance of the proffer *or otherwise present a position inconsistent with the proffer*") (emphasis added).

In *Lopez* (cited by the government, Gov. Mot. at 9), just as here, the government relied on Seventh Circuit cases to contend that *argument*, not testimony, triggered a waiver provision in a proffer agreement. The Fourth Circuit *rejected* the government's position, precisely because the proffer agreement did not contain the "otherwise presented a position" language that made a difference in the Seventh Circuit. *See Lopez*, 219 F.3d at 346. Just as in *Lopez*, this Court should look not to Seventh Circuit cases interpreting proffer agreement language that is standard in that circuit, but instead to the language of *this* agreement, which does not contain that provision.

The waiver in this agreement is triggered “should she **offer** in any proceeding statements or information different from” that provided during her proffer. Gov. Mot. at 9 (quoting agreement) (emphasis added). “Offer[ing]” “statements or information” “in any proceeding” connotes offering those statements or information *in evidence*. See, e.g., Black’s Law Dictionary 1081 (6th ed. 1990) (“**Offer**, v. . . . In trial practice, to ‘offer’ evidence is to state its nature and purport . . . and demand its admission.”); 1 Wigmore, *Evidence* § 17 (Tiller rev. 1983) (describing the offer of evidence); 1 Brown *et al.*, *McCormick on Evidence* § 51 (6th ed. 2006) (same).³ Thus, the waiver is triggered only by Ms. Stevens’ *offering evidence* at trial.⁴ As the Fourth Circuit admonished in *Lopez* (and as every trial court admonishes in jury instructions), statements, objections, and argument by the attorneys are not evidence. See *Lopez*, 219 F.3d at 347. Thus, contrary to the government’s position, arguments by counsel do not trigger the waiver provision in Ms. Stevens’ proffer agreement here.

Second, the waiver in Ms. Stevens’ proffer agreement is “for purposes of cross-examination and/or impeachment” only, and is triggered if “*she offer[s]*” statements or information inconsistent with her proffer. Gov. Mot. at 9 (quoting agreement) (emphasis added). The “she” in this instance is Ms. Stevens. The waiver language is triggered if “she,” Ms. Stevens, testifies and gives information inconsistent with her proffer. It is designed, in other words, to

³ See also, e.g., *United States v. Blake*, 571 F.3d 331, 350 (4th Cir. 2009) (Federal Rule of Evidence 804(b)(3) “places a ‘formidable burden’ on those seeking to *offer evidence* pursuant to that rule”) (emphasis added); *United States v. Jeffers*, 570 F.3d 557, 568 (4th Cir. 2009) (to obtain instruction on inferring consciousness of guilt, “the prosecution *must offer evidence* supporting all the inferences in the causative chain”) (emphasis added, citation and internal quotation marks omitted).

⁴ To the extent the government might contend that the meaning of “offer in any proceeding statements or information” is ambiguous and could arguably reach arguments by counsel, such ambiguity is construed against the drafter, here, the government. See cases cited *supra* at 12.

allow the government to rely on her proffer and to impeach her if she later testifies inconsistently with it. Thus it is triggered only if Ms. Stevens testifies, and applies only to the government's cross-examining Ms. Stevens or impeaching her testimony.

To the extent one could argue that the reference to information "she offer[s] in any proceeding" could apply to information offered either by Ms. Stevens or her counsel, this shows only that the meaning of "she" is ambiguous—it could mean Ms. Stevens personally, or it could mean Ms. Stevens and/or her counsel. Had the government meant the waiver provision to have the latter meaning, it could easily have said so expressly. *Compare, e.g., Harvey*, 791 F.2d at 301-02. It did not do so, however. In these circumstances the term "she" is ambiguous, admitting of two plausible meanings. This ambiguity is construed against the drafter. *See Harvey*, 791 F.2d at 300-01, and other cases discussed *supra* at 12. Thus, the waiver provision is triggered only if Ms. Stevens testifies inconsistently with her proffer. If she does, the government may use her proffer statement to cross-examine and/or impeach her. If she does not, the government may not use her proffer statement at trial.

This issue need not be decided unless and until Ms. Stevens (or, arguably, her counsel) actually introduces evidence that arguably triggers the proffer agreement's waiver provision. Should the government reach a point where it contends that the waiver provision has been or is about to be triggered, it should bring the matter to the Court's attention so that it may be addressed before an arguable waiver arises.

Respectfully submitted,

Dated: March 21, 2011

By: /s/
Reid H. Weingarten
William T. Hassler
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795
(202) 429-3000

Brien T. O'Connor
Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
(617) 951-7000

Colleen A. Conry
Ropes & Gray LLP
One Metro Center
700 12th Street, NW, Suite 900
Washington, DC 20005-3948
(202) 508-4600

Counsel for Defendant Lauren Stevens